UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, ex rel. JULIE LONG, Plaintiffs	)	Civil Action No. 16-12182-FDS
vs. JANSSEN BIOTECH, INC., Defendant	)	

BEFORE: CHIEF JUDGE F. DENNIS SAYLOR, IV

MOTION HEARING CONDUCTED BY ZOOM

John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

May 18, 2023
11:00 a.m.

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PROCEEDINGS

THE CLERK: Court is now in session in the matter of United States vs. Janssen Biotech, Civil Action Number 16-12182.

Participants are reminded that photographing, recording or rebroadcasting of this hearing is prohibited and may result in sanctions.

Would counsel please identify themselves for the record, starting with the plaintiff.

11:01AM MR. LEOPOLD: Good morning, your Honor, Ted Leopold, Leslie Kroeger and Casey Preston on behalf of the relator and Gary Azorsky, I'm sorry.

THE COURT: Good morning.

MR. LEOPOLD: Good morning.

MR. DUNN: Good morning, your Honor, Matthew Dunn from Covington & Burling on behalf of defendant Janssen Biotech, Inc. I'm joined by my colleagues Jason Raofield and Laura Wilk.

THE COURT: Mr. Dunn, you're a little far away from

11:01AM the camera, and the mic. seems to be a little weak, actually the volume is, what I'm particularly concerned about, if you could somehow pick it up or move the mic.

MR. DUNN: Bear with me one second, your Honor, while I get that sorted. Is that better, your Honor?

THE COURT: Yes, it is, thanks.

MR. DUNN: Thank you, your Honor.

THE COURT: This is a hearing on Janssen's motion for a judgment on the pleadings. Mr. Dunn, I think it's your motion, I assume you're taking the lead?

MR. DUNN: Yes, your Honor, thank you.

THE COURT: All right, go ahead.

MR. DUNN: So, as your Honor knows, this is Janssen's motion for judgment on the pleadings, and we respectfully ask the Court to dismiss relator's three remaining claims pursuant to the public disclosure bar under the False Claims Act. Under the well-developed case law and the record here, dismissal pursuant to the disclosure bar is clearly warranted.

The First Circuit has stated that the ultimate inquiry of the public disclosure bar is whether the government has received fair notice prior to the suit about the potential existence of the fraud. The answer here is clearly yes.

What is relator's case about?

THE COURT: Doesn't it really turn on what the statute says, right, and the statute says the government has to be a party or an agent. I mean, you could publish it on the front page of the New York Times, and, you know, that wouldn't satisfy the statute, at least the part about the government being a party or an agent being a party, right? Doesn't it kind of turn on whether the statutory requirement has been satisfied?

MR. DUNN: Yes, your Honor, that is the second part of the *Winkelman* test. If it was on the front page of the New York Times, it would be a separate type of disclosure, it would be in the news media.

THE COURT: Right.

MR. DUNN: For our purposes, it is whether it is a federal civil hearing in which the government or its agent was a party, so, your Honor, I'll start with because we have different disclosures here, I'll start with the two qui tams, the *Heineman* and *Greer* cases that we referenced.

11:03AM

On those, the United States is in the caption. The best reading of the statute is that relator is at least the agent of the government in such cases even if you don't consider the government a party in a declined qui tam case.

The weight of the authority supports this reading. We cite the Sixth Circuit case, *Holloway vs. Heartland Hospice,* and we cited other cases, which followed the *Holloway* lead. *Holloway* states, quote, "Because the government is the real party-in-interest, the relator is the assignee of the

11:04AM

government's damages claim, and the government exerts a fair amount of control over qui tam litigation. A qui tam relator is in all cases the government's agent under this portion of the public disclosure bar."

It also asks the very good question, "Who, if not the private relator, is the government's agent?" So even in a

qui tam case, the relator still pursues the action on the government's behalf, and the government always remains the real party-in-interest. The government gets the filings, it maintains a degree of control, it can dismiss, it can get involved in settlement, et cetera.

So, you know, we cite other cases in our briefs that land the same way as *Holloway*, including and one, you know, that we didn't cite, but there's more, there's *U.S. ex rel. Folliard v. Comstor Group*, 308 F. Supp. 3d 56.

11:05AM Relator cites one outlier case, *Medtronic*, and we respectfully, for the reasons stated in our papers, believe that that case was incorrectly decided. We do not believe there's any reason to depart from the Sixth Circuit on this.

THE COURT: One of the many odd ball things about this is the statute could easily use the word "relator," but it doesn't, it uses the word "agent," which normally, you know, has a well-established meaning of, you know, an agent has agency from the principal to do various things.

That's one of the things I'm struggling with here is

11:06AM it's a fair point, who, if not the relator is the government agent, but, of course, it doesn't use the word "relator," so what am I supposed to do with that?

MR. DUNN: Your Honor, I believe that the reading of "agent," they didn't use the word, "relator," you're correct. I believe that the reading of "relator" to include, "agent,"

I'm sorry, your Honor, to include "relator" is the best reading of the statute, and the best way to effectuate the purpose of the public disclosure bar, which is, again, to identify instances in which -- I'm sorry, bear with me for a moment -- the ultimate inquiry, which is whether the government has received fair notice prior to suit about the potential existence of the fraud.

Qui tam cases are sent to the government by statute. They are required to investigate those cases. That's a statutory requirement of the False Claims Act. The government has to make a decision whether or not to decline or intervene. The government is certainly on fair notice of claims that are brought by a qui tam relator.

THE COURT: All right. Continue.

MR. DUNN: Your Honor, so now I will turn to what I'll call the *AWP* case. The only courts to have considered the question that we are aware of in the post-amendment context, so after the public disclosure bar was amended in 2010, have correctly determined that *AWP* is a qualifying public disclosure, that's the *CSL Behring* in the Eastern District of Missouri and the Eight Circuit's affirmance in 2017 in which the Court held that the *AWP* litigation constitutes a disclosure made and a qualifying source.

Those, importantly, your Honor, those decisions related to the exact same action within the MDL that's at issue

here. CSL Behring was a co-defendant of Janssen in that matter, and respectfully, your Honor, we believe those courts got it right.

The government was listed on the docket as an interested party. The statute doesn't say what type of party, and, moreover, in keeping with the purposes of the statute, the government was a party in all the way that matters for purposes of the public disclosure bar, which is that it received fair notice.

11:08AM The government received all the filings in the *AWP* case. That includes what I'll probably get to later, which is the deposition testimony of Mr. Hoffman, a vice-president of Centocor, which was listed on that docket. The government actually participated in the multi-district litigation, including making filings that were applicable to all motions.

And, your Honor, I would just point out that the government received far more notice through the *AWP* MDL in which it was an interested party in what you would typically receive from one of the statutory methods that you referred to

11:09AM earlier, the news media.

Oftentimes, there's no reason to think at all that the government might actually know or be on notice about, you know, a random news article or publication, you know, that may be obscure, but it counts for disclosure, nonetheless.

Here, there was actual disclosure to the government --

sorry, your Honor, the phone is ringing -- here, there was actual disclosure to the government because the government chose to join the MDL and be listed an an interested party.

Not treating *AWP* as a qualifying public disclosure would be inconsistent with the statute and its purposes. We don't believe there's any reason to depart from the Eighth Circuit on this.

THE COURT: Again, "party," "party," like "agent," you know, is a word that has a well-established meaning. I mean, you know, we have rules about this, you know, are you an indispensable party? Are you the real party-in-interest? We basically have two kinds of parties, plaintiffs and defendants, putting aside cross-claim plaintiffs and counterclaim plaintiffs and all of that.

And, you know, in other words, it's a term of art, you're either a party or you're not, you're either in or you're out, and there's no halfway in, at least in other contexts, and, again, I agree that as a practical matter the government is participating as an amicus or whatever is they were doing. They may have actual notice, but that's not really what the statute says, the statute says you have to be a party.

MR. DUNN: Correct, your Honor, it doesn't say interested party, it does say party. I do believe that the Eighth Circuit was correct though in finding that the government was a party for purposes of this statute and how

parties should be interpreted within the public disclosure bar statute, which, again, the purpose of it is about notice to the government and where the government actually received notice in a federal court litigation in which it has chosen to be on the docket and be an interested party and receive the information.

You know, it's not something where the government didn't receive the information, you know, it received the filings on the docket that the best reading of the statute is that you're a party under those circumstances.

11:11AM THE COURT: Okay, go on.

MR. DUNN: So, your Honor, I'll kind of turn back to the beginning here, and in a moment, I'll go through the *Winkelman* test, the three-part test. We just covered the second part. But, again, I'd like to step back. Here's how relator described the so-called scheme in paragraph 5 of the second-amended complaint.

Relator alleged that the company provided the services to help the practices establish infusion suites so the practices would directly administer Remicade and SIMPONI Aria

11:12AM infusions, and then once opened, to help practices operate the infusion businesses more efficiently and profitably so the practices would grow their infusion businesses by prescribing and infusing more Remicade or SIMPONI Aria and the first part of the *Winkelman* test, your Honor, is whether the essential elements about the alleged scheme have been disclosed.

That Janssen was engaged in this type of conduct was no secret. It was openly disclosed, and I'll take you through both *AWP* and the qui tams, your Honor.

So, in *AWP*, John Hoffman, he's not some low-level employee, he's a vice president at Centocor, and he testified as follows: And you will hear it sounds remarkably similar to the summary of relator's allegations that I described to you. There were significant complexities associated with not only setting up initially an IOI position office on an ongoing basis, making sure that the billing, coding, reimbursement, scheduling, handling of infusion redactions, all of the things associated with it were addressed.

As a result, Centocor established a practiced management program, which was designed, quote, "to provide education and tools to physicians to help them not only get over some of these disincentives and obstacles that they had but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis, as well as helping physicians analyze the financial implications and how to do coding, et cetera.

These, in summary, they stated that Janssen was providing information to assist with opening and optimizing IOI infusion suites. Relator attempted to diminish these disclosures, such as on page 17 of its opposition brief in which it said there was no disclosure that Janssen provided

practiced management programs that had independent value beyond Remicade or that the doctors did not have to pay to attend the valuable programs.

That's just not correct, as I just read Janssen's VP testified about the practiced management program. Judge Saris used those very words in her opinion in the *AWP* bench trial. She wrote, quote, "Centocor developed and implemented a practiced management program to educate physicians on buying, infusing, and billing for Remicade." "Infusing." Judge Saris understood that that was -- part of the practice management program was about based on the record in that case.

11:15AM

Your Honor, I won't belabor it. You have Exhibit I to our brief, but I know there's a lot of paper that you've been provided with in connection with this motion, so I wanted to point you to that because it shows that relator's other arguments that the prior disclosures were just about *AWP* and marketing spread, that's just incorrect.

We're going to try, and I hope we don't mess up the tech, your Honor, to share one slide with you quickly. And if that's hard to see, your Honor, I'm going to summarize it.

11:15AM

THE COURT: I can --

MR. DUNN: I'm sorry, your Honor.

THE COURT: I can see it.

MR. DUNN: Okay, thank you. This is the office-based infusion guide that was disclosed in the *AWP* case. It's not

just about marketing the spread or inflating prices. As you can see, just from the table of contents, and then the guide goes through it, it has a ton of information about opening and optimizing IOI. It talks about resource evaluations, the space requirements, essential and operational infusion suite equipment, the necessary administration supplies, the staff, training and certification that would be necessary if you were to open an IOI suite, how to optimize your resources. It goes on to talk about the timing of infusions, maximizing efficiency, and then patient comfort, the types of things relator talks about here, eating, drinking, entertainment options, the setup.

11:16AM

The guide goes through that. It is not just about *AWP*. It clearly disclose that the company was involved in providing information about opening and optimizing IOI suites.

THE COURT: But somebody, you know, looking at this information would need to draw, take the next step, in other words, this is litigation about wholesale pricing, it's not a litigation about kickbacks or false claims, so somebody would

11:17AM

have to look at this and not only understand the fact pattern but also say, ugh, this may constitute a kickback or this may result in a false claim, right? In other words, the words "kickback" and "false claims" are not present in *AWP*, right?

MR. DUNN: No, it is a case about fraud against Medicare, right, in general, it's that AWPs were inflated

fraudulently causing the government, and, in this case, the private payors, to pay more than they otherwise would have.

But, you know, a few things, your Honor, in response to that. First, *Winkelman* forecloses the argument that you have to use magic words like fraud. It says, quote, "The public disclosure bar contains no requirement that a public disclosure use magic words or specifically label disclosed conduct as fraudulent."

It also states that a relator's ability to recognize the legal consequences of a publicly-disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed, and what I would argue, your Honor, is that relator states that providing, broadly speaking, providing information about how to open and optimize office infusion suites is unlawful remuneration. That's what the case is about.

So once you disclose, it wasn't an allegation, but it was disclosed that they were providing that type of information by the company. That is more than enough to put the government or anyone else on the trail of fraud if you believe relators' theory that this is somehow fraudulent.

And, your Honor, bear with me for a moment. I would just add that even without *AWP*, the prior, previously filed qui tams, *Heinemann* and *Greer* standing alone put forth the essential elements. They state, for instance, that Janssen

improperly marketed Remicade by hiring individuals with the position entitled reimbursement specialists, who conducted business reviews, and they provided independent consultants to advise providers on how to run a profitable practice and promote the business using Remicade. That's not in a vacuum, your Honor.

There's this additional allegation in the *Heineman* complaint. They state not only were they providing business reviews and independent consultants, but, quote, "The defendants also marketed the product Remicade by funneling money into positions of offices through the use of preceptorships to assist physicians in acquiring infusion chairs and establishing infusion suites to allow for their administration of the drug."

So, pulling that together, you have an allegation they're providing reimbursement specialists, business reviews, independent consultants about how to run their practices, and in another allegation relating to what I'll broadly call IOI support, it's far more serious than the allegations put forward in this case, which is that they were actually purchasing the equipment for the practice, providing them the money, providing them the equipment so they could open it.

So it was out there that there were allegations that Janssen was improperly involved in setting up and providing information about IOI infusion suites, and that alone is enough

to put the government squarely on the trail of fraud.

Your Honor, relator makes several arguments that these are not sufficient, that they're unavailing under the case law, the well-established case law in this circuit.

First, relator argues that we've just pulled out snippets from different matters. *Winkelman* disposes of this, quote, "The set of facts publicly disclosing an alleged fraud may originate to different sources, as long as they lead to a plausible inference of fraud when combined."

11:21AM Second, relator alleges that, you know, that the words "fraud" and other similar words involving a legal conclusion were not used in the prior disclosures. As I pointed out earlier, your Honor, *Winkelman* forecloses this argument. It says that there's no requirement for magic words and there's no requirement that just because a relator can recognize the legal consequences of a disclosed scheme, that does not suffice to say that they are not, that there has not been a public disclosure.

Furthermore, on that point, your Honor, two of the 11:22AM cases are qui tam complaints, which by their nature relate to fraud. Both of those claims allege that there's kickbacks that led to violations of the False Claims Act, and *AWP* was a case about Medicare fraud.

Third, and, finally, your Honor, relator argues that Janssen somehow mischaracterized the record. That's just not

so. The things that we cite speak for themselves. We accurately quoted them. They're quoted in the brief side-by-side with relator's allegations. We have a chart on page 19 to 22 of our opening brief that I would defer your Honor to, but they're accurate.

We're obviously accurately quoting the information. Your Honor, I'll skip step 2 of *Winkelman* because we've already discussed it, unless you have more questions on it, and that's whether or not it was in a qualifying source.

11:23AM I'll move onto step 3 of *Winkelman*, which is I'll call it the substantial similarity test. You compare the substance of the prior disclosures with the substance of the relator's complaint and see if they're substantially similar. This does overlap, I think as relator acknowledges well. It overlaps significantly with the inquiry under step 1, but it is a different part of the test.

Winkelman focuses on the term "anatomy of the scheme." If the anatomy of the scheme has already been revealed, a new complaint that targets the same scheme is barred, even if it 11:23AM offers more details. That is on all fours with our situation. The fact or the allegation, the information that Janssen was providing information concerning opening and optimizing IOI suites was in the public domain long before this complaint was filed.

It's the exact same scheme, alleged scheme, I should

say, that has been in place continuously, according to the relator's complaint, from 2003 to 2016. Relator merely alleges that that scheme has evolved, but a scheme just adding more details or color under *Winkelman* is not enough.

Again, your Honor, disclosures only need give rise to an inference of fraud and set the government on the trail of fraud. *U.S. ex rel. Poteet*. That's a First Circuit case from 2010. That's very instructive on the substantial similarity inquiry.

11:24AM There, the earlier filed case, which served as the public disclosure, alleged that Medtronic had been providing essentially bribes, you know, money to doctors in exchange for use of the products.

The later filed case, *Poteet II*, we'll call it, that's this *Poteet* case, the Court said it added, you know, one new allegation, and that was that the defendant had engaged in off-label marketing to encourage off-label use and also encouraged that, you know, off-label uses were reimbursable by Medicare under -- I know your Honor is quite familiar with

11:25AM these types of cases, and, you know, normally one might think of paying a bribe and providing off-label information, off-label promotion are two different things, but, here, the Court said it's part of the same overall scheme, which is that it's substantially similar because it's the same scheme to induce action by doctors for improper scripts.

And it held that, you know, although those off-label allegations added some color, that was the word it used, they ultimately targeted the same overall scheme.

Banigan is also quite instructive, your Honor. That's a First Circuit case from 2020. There, the Court found relator's allegations were substantially similar even though they included a longer period of time, implicated a different kind of remuneration, applied two additional drugs, and utilized, quote, "different, more regressive tactics."

11:26AM That's a lot of what relator argues here makes it not substantially similar. They point to the addition of SIMPONI, but they point to -- but there's no reason to believe that's a different scheme, it's the same, it's just a different drug with the same alleged scheme applied to it as described by relator. And then they add more color and more information about specific tactics. They say the company got more aggressive over time.

That's exactly what *Banigan* said is insufficient, so unless you're -- you know, and relator didn't speak to even 11:27AM distinguish these cases or grapple with them, and I believe that's because relator is not.

Your Honor, unless you have questions on that piece, I'll move onto the original source.

THE COURT: All right.

MR. DUNN: Thank you. Very quickly, the key here, the

part of the statute we're dealing is whether or not it materially adds to what was publicly disclosed, and it must be before she filed this action.

Winkelman lays out the framework again, and it's very clear. It says the task is to ascertain whether the relator's alleged new information falls into, quote, "The narrow category of information materially asked," says that adding detail for color to previously disclosed elements is not enough. It says that trumping one's personal knowledge or adding specific

11:27AM examples of the conduct does not provide any significant new information where the underlying conduct has already been disclosed.

And, again, your Honor, it says that merely adding detail about the precise manner in which a company operated the program and a relator who merely adds detail or color, again, that's not materially adding anything.

Finally, *Winkelman* says that adding information that is easily inferable, okay, that's insufficient, easily inferable from the prior public disclosures.

11:28AM So, you know, I'm not going to go through each of relator's alleged material additions, but I'll discuss a couple. You know, relator says she provided information based on her knowledge from 13 years. She says she provided specific and detailed information concerning the IOI support. She says that she, you know, added the insight that these might have

substantial and independent value, but there is no new alleged scheme. She didn't allege a new scheme, she merely added color.

With respect to substantial independent value, that's not even a new fact, that's a new conclusion, and, if anything, it's a consequence of the underlying scheme, it's not a new scheme.

Two others, your Honor, relator argues that the, you know, conduct continued for years. That's foreclosed by *Winkelman* where there's, quote, "Every reason to think that a scheme would continue," given that the company had already indicated that it was engaged in the conduct.

11:29AM

And, finally, she, I'll point out that the relator states that she has made a material addition relating to scienter. Again, *Winkelman* dealt with that in this context where a company has already stated what it is doing. You're not, you know, adding materially adding where, you know, you argue that the company is kind of doing it intentionally when the company has already indicated it's engaged in certain conduct.

11:29AM

Your Honor, I know I've been going for a while now. Unless you have questions, I can turn it over to relator's counsel. I would just -- go ahead, your Honor.

THE COURT: I doubt this has any legal significance, but I'm just curious to know the response. The relator's lead

off with the proposition that, you know, this is a Hail Mary, this is years into the litigation. Again, I'm not sure that makes a difference legally, but I'm curious to know your response to that.

I mean, I would maybe frame it this way. If a new qui tam were filed in Ohio tomorrow on, you know, Remicade and SIMPONI and IOIs, I'm sure you'd say, no, hold it, you know, we've been down this path, this is barred by the prior disclosure doctrine, and you say that this is round four, you've got the two qui tams never went anywhere plus *AWP*, and, you know, why wasn't this let's say a 12(b)(6) motion right off the bat if this is so obvious?

11:30AM

MR. DUNN: Understood, your Honor. So, first, it has no legal relevance. Relator has some rhetoric in the opening portions of her brief, but she doesn't argue that that's a legally relevant question in terms of timing. It is a timely motion. You can bring a 12(c) motion any time, yu know, after you answer, it won't delay trial, and that's what we've done here.

11:31AM

With respect to why it wasn't raised at the motion to dismiss stage, your Honor, you know, all I can say is defendants make strategic decisions all the time about what arguments to include and not include, and that doesn't necessarily reflect, as I'm sure your Honor appreciates, their belief on the argument on the merits. Companies frequently

wait until summary judgment to raise a public disclosure argument. What I can say here is, you know, I'm newer to the case, but I do know that there was a thought that summary judgment might be occurring earlier than it has, and at this point, it's much more efficient to raise this argument now than wait for summary judgment, and so that's what we've done.

THE COURT: Okay. All right. Mr. Leopold, are you taking the lead?

MR. LEOPOLD: Your Honor, Mr. Preston is going to be arguing for the relator in this particular matter.

11:32AM

THE COURT: Okay, Mr. Preston.

MR. PRESTON: Good morning, your Honor. I obviously want to go through all the points why Janssen's motion doesn't satisfy the public disclosure requirements, and clearly the original source exception applies here, but on that last point, you know, Mr. Dunn talked about there was some strategy behind waiting, which, frankly, really makes no sense given all the discovery that's taken place, but I just want to bring to your Honor's attention, and this is set forth in the declaration we provided with our opposition, Exhibit 1, in discovery, right off the bat, we issued an interrogatory asking Janssen to identify all cases involving any kickback claims brought against it, right? It didn't identify *Heinemann or Greer* or *AWP*, it identified two cases that Mr. Dunn hasn't referenced today. We sent out that interrogatory at the very beginning of

11:33AM

discovery.

Finally, in I believe it was March of 2022, well into discovery, that Janssen, and, again, your Honor, this is over a year ago that Janssen identified *Heineman* and Greer claiming that it wasn't even aware, so I'm not sure how this could possibly be a public disclosure here if Janssen wasn't even -- these cases really didn't even -- it didn't believe they were significant enough to even put in their response to our interrogatory.

11:34AM THE COURT: But isn't that just kind of rhetoric? I mean, like again what legal consequence flows from that? It would not surprise me given how far back these things are, you know, that different law firms were involved, maybe in-house counsel.

I'm constantly confused here by what's Janssen, what's Centocor, what's Johnson & Johnson, but I imagine there's a lot of turnover and different counsel involved, but the real point being what legal consequence flows from that, if any? The motion is not untimely in the sense I'm going to dismiss it on

11:35AM that basis. I don't hear you saying that this needs to wait for summary judgment because these are not matters at which, you know, the filings in those cases are not things that I can consider, so, you know, the bottom line is the statute says what it says, and either this fits or it doesn't, right, isn't that the framework I'm supposed to analyze this under?

MR. PRESTON: That's correct, your Honor, I think the point is that the whole analysis is whether these allegations and information from these really old cases put the government on notice of the fraud, and, right, and if Janssen isn't even highlighting them in their original motion to dismiss or in the discovery, clearly they weren't obvious public disclosures. That's really the point, your Honor.

THE COURT: All right. But, and, again, one of the many odd ball things about this, it's not subjective. You don't have to point to some person in the government or for that matter Janssen who says, ugh, I knew about this, it's objective, what was the information that was out there, right?

MR. PRESTON: Yes, your Honor.

THE COURT: That's the standard, for better, for worse.

MR. PRESTON: I'm sorry to get sidetracked, I just wanted to address that point.

THE COURT: Okay.

MR. PRESTON: By the way, your Honor, Covington & Burling has been representing Janssen from the very beginning. This isn't a case where there's been turnover in law firms, there's been turnover amongst Covington & Burling's team on this case, but --

THE COURT: I'm shocked to hear that.

MR. PRESTON: But they have handled this case from the

beginning.

Your Honor, the public disclosure theory that Janssen has gone to great lengths to construct streaming together a few vague and innocuous assertions and allegations from these three lawsuits that predate March of 2007 and are focused on completely different conduct is meritless, and it meets none of the False Claim Acts' prepublic disclosure requirements, and even if the asserted disclosures did meet the statutory requirements and they were found to be enough to put the government on notice of the fraud alleges, we strongly assert that it's not, but if that were the case, the motion still fails.

11:37AM

The relator, who participated in the alleged kickback scheme for 13 years, she provides numerous material additions to any disclosure that ay have occurred. Ms. Long clearly meets the original source exception to the public disclosure bar.

As your Honor observed in the *Hagerty* case, the purpose of the public disclosure provision is to prevent parasitic qui tam actions, and I'm quoting this, to prevent parasitic qui tam actions in which relators rather than bringing to light independently discovered information of fraud simply feed off of previous disclosures of public fraud. A comparison of the relator's allegations and this collection of information and allegations that Janssen 's pieced together

11:38AM

clearly demonstrates that the relator's allegations are not parasitic.

If the fraud relator alleges had actually been previously disclosed, Janssen's counsel could directly point to it and would have raised this argument in its motion to dismiss filed three years ago, not now, two years into discovery, and, in fact, again, Janssen didn't even view most of the asserted disclosures, most of which relate to marketing the spread, a practice from the late '90s and early 2000's, which Judge Saris concluded ended in December of 2003, when Congress changed the payment system to stop the abuse that they're not -- Janssen determined that they weren't of sufficient relevance to produce and identify them in discovery before filing this motion.

11:39AM

Your Honor, I'm going to just briefly address why Janssen's theory doesn't meet the public disclosure provisions requirements. To start, the asserted disclosures weren't made in a federal proceeding in which the government or its agent was a party, as the public disclosure provision requires.

Starting with the *AWP* class action, none of the parties in that case were agents of the government, and the United States clearly was not a plaintiff or a defendant to that action. And as your Honor pointed out, Janssen's argument ignores the ordinary meaning of the term "party" and that Congress amended the statute to narrow the judicial proceedings that can be the source of a public disclosure.

11:39AM

Janssen argues that the government should be treated as a party to the *AWP* class action because it was noted on the docket as an interested party because it received copies of filings and because it may have submitted some briefing.

Well, those limited connections don't make the government a party to the action. For example, in a non-intervened qui tam, the government is the real party-in-interest. It receives copies of all the filings, it submits filings and oftentimes some briefing, but the Supreme Court held in the *Eisenstein* case that this is not enough to make the government a party to a non-intervening qui tam.

Because the government was not a party to the *AWP* class action and the parties to that action were not agents of the government, none of the information and allegations from that lawsuit can constitute public disclosures.

Mr. Dunn talked about the *CSL* case from Missouri and the Eighth Circuit's affirmance of that case. Well, in that case, the relator was making an argument very similar to marketing the spread, and it was clear that that scheme had been publicly disclosed, and the relator never objected that the Court considered that information because it was essentially a moot point.

So to the extent that those courts considered information from the *AWP* class action, it was erroneous.

That's certainly not binding on this court, and it really shouldn't even be persuasive to this court.

Likewise, your Honor, in the *Heineman* and *Greer* qui tam actions, those aren't qualifying federal proceedings under the public disclosure provision.

The government declined to intervene in both of those qui tams, and, therefore, it wasn't a party to those cases. The few courts that have considered whether a relator in a non-intervening qui tam constitutes an agent of the government, they've reached different conclusions, and we talked about those earlier.

11:42AM

Again, we submit that the Eastern District of Pennsylvania's decision in the *Forney* case is the appropriate analysis. The government is not paying the relator a fee to act on its behalf. The relator has a separate interest in the case's outcome. The government does not control the litigation. The typical agency relationship doesn't exist here, and, again, Congress specifically selected the term "agent." It did not include relators.

11:42AM

The argument from Janssen ignores the ordinary meaning of the term "agent."

THE COURT: I certainly understand that argument, but as I think it was the Sixth Circuit pointed out in *Holloway*, is that the name of the case, that if the relator isn't the agent, who is, who could that possibly apply to? Can you name a

person or an entity that might be an agent under these circumstances that, you know, to which the disclosure bar might apply? I'm kind of scratching my head here trying to think of some category of agent. It can't be a government employee. I mean, that's theoretically an agent of the government, but it can't be that.

MR. PRESTON: Your Honor, this is a practice area of our law firm where we represent Attorney Generals in bringing cases. They sometimes hire outside counsel to represent them or, you know, there could be cases where they allow a public interest group to represent the government's interests in a case.

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The False Claims Act does not have that type of a construct, and, in fact, the government tells the relator not to act on its behalf, right? This is a very different type of relationship than your typical agency relationship, and Congress chose the term "agent," and they did not take into account, they could have, they could have specified that it would apply in a qui tam action, they chose not to, and there's no basis to expand the term "agent" to include nonagents, such as relators.

THE COURT: But basically you think I should follow the *Forney* case as opposed to *Holloway* on this point, right, I mean it kind of comes down to that, which court got it right?

MR. PRESTON: Your Honor, we believe that the *Forney*

case is the more appropriate analysis, and we believe that the *Forney* cases also consistent with the Supreme Court's analysis in the Vermont case that's cited in the *Forney* action.

THE COURT: Wasn't the Judge in *Forney* in the Eastern District of Pennsylvania unduly suspicious of people who may be Eagle's fans or people of that ilk? Should I take that into account, maybe drop a footnote?

MR. PRESTON: That's a fair concern, your Honor, but I think that Judge Smith is someone who you can rely on his analysis, and he's certainly objective.

Kidding aside, your Honor, I think his decision in *Forney* is well reasoned, very thoughtful, and appropriate here, and we believe that it's the more appropriate analysis than the Sixth Circuit's analysis in *Holloway*.

THE COURT: Continue.

MR. PRESTON: So, again, the government was not a party to *Heineman* and Greer. The relators were not agents of the government, and so the asserted disclosures from those actions cannot constitute public disclosures.

Even if the three earlier cases were qualifying federal proceedings under the public disclosure provision, the fraud, your Honor, that the relator alleges still wasn't disclosed in those cases.

Janssen manufactured its public disclosure theory by taking pieces of information and assertions that, frankly, had

unearthed from the *AWP* class action and has pasted them together with a few vague allegations from the *Heineman* and *Greer* complaints, two cases that really went nowhere, and under the First Circuit law, this collection of outdated information of allegations and assertions only constitutes a public disclosure if it provides sufficient information concerning the essential elements of the fraud that relator alleges, such that the government should have already been on notice of that fraud.

11:47AM And, importantly, and as your Honor recognized in the *Flanagan* case, in order to be a disclosure of fraud, the disclosure must contain either a direct allegation of fraud or both misrepresent a state of facts and a true state of facts such that the fraud may be inferred, and that's not the case here. None of the three earlier cases allege the fraud relator alleges.

When the asserted disclosures are read in their original context, not quoted, and selectively quoted and paraphrased and pieced together and then compared to the

11:48AM relator's allegations, it's clear that they wouldn't have put the government on notice of the fraud relator alleges.

Relator's allegations concern Janssen's strategy and practice of having its special team of practice advisors called area business specialists as well as outside consultants such as Xcenda, advised physician practices on how to open an IOI

and assist them with getting it up and running.

And even more significantly in order to gain the loyalty and grow and maintain sales of its products of that IOI, Janssen had the area business specialists and the outside consultants regularly provide the select IOI accounts, not all accounts, but just select IOI accounts, practice management, and infusion business advisory services and support on a wide range of topics that had broad value, such as increasing IOI infusion volume and capacity, enhancing the IOI, optimizing infusion scheduling and staffing, negotiating higher reimbursements from insurers, managing relationships with insurers, tracking payments from insurers and patients, developing standard operating procedures to optimize the IOI work flow, managing drug inventories, qualifying for incentive payments under the government's incentive programs.

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In our briefing, we collectively refer to this package of infusion business services and support, which are the alleged kickbacks in this case that are at issue as the IOI support. And relator alleges that the IOI support had substantial and broad value beyond Remicade and SIMPONI Aria. Relator also reported that Janssen regularly provided these services to select IOI accounts for free in order to induce the doctors to prescribe and infuse Remicade and SIMPONI Aria to Medicare patients.

On the other hand, the information, allegations and

assertions from the three earlier cases don't allege any of the essential elements of the fraud relator alleges and much less even suggests that Janssen provided the IOI support at issue.

The three earlier cases focused on fundamentally different conduct, such as: Marketing the spread, which is the *AWP* class action and the *Heineman* case; underpayment of rebates to the government, that's *Greer;* off-label marketing, that's *Greer*; kickbacks from the scheme that were different from the scheme alleged here, such as paying doctors cash bribes to help them open the IOI and to utilize or prescribe Remicade. There's no allegation in our case about paying bribes to doctors or giving them financial support for the IOI.

11:50AM

In *Heineman*, it talks about paying doctors for attending advisory board meetings at luxury resorts and sham research and education grants. That's outside the scope of what we've alleged.

We've submitted as Exhibit 2 to our brief a table that lists the information and allegations from the other cases that Janssen contends constitute public disclosures. And this exhibit also provides additional context. It's not all of the context that can be read in those exhibits that Janssen provided and relies on, but they show how Janssen mischaracterized some of these asserted disclosures by paraphrasing and quoting them out of context.

11:51AM

Under the framework that the Court applied in

assessing whether relator's complaint states a plausible anti-kickback violation, in order for services to constitute illegal remuneration, they must have substantial independent value. They must be provided for free or significant discount.

One of the purposes of providing the services must be to induce prescriptions to Medicare beneficiaries, and the services must have been provided knowingly and willfully.

In addition, it's critical that the recipients of the services must have subsequently prescribed the drugs and sought payment from Medicare. The vague references to practice and management program, business review and consultant in the three earlier cases weren't accompanied by these essential allegations for information that would have made the government aware of the elements of the fraud relator alleges.

11:52AM

In addition to not even asserting a kickback claim based on these activities, there's no allegation that Janssen's predecessor, Centocor, had employees and consultants regularly provide the referenced program and business review to select IOI accounts. There's no allegation that the reference program and business review had substantial value beyond Remicade.

11:53AM

There's no discussion of the value of the reference program from those cases. There was no allegations that the doctors didn't have to pay for that reference program. There's no allegation that the reference program and business review weren't provided to all doctors but rather only to select high

volume and targeted accounts. There was no allegation that the factual support or providing factual support that Janssen's predecessor Centocor knew that providing the reference program and business review was illegal. There's no allegation that the physicians who received the reference program and business review subsequently prescribed Remicade and submitted false claims to Medicare where they falsely represented that they weren't accepting illegal remuneration.

And now apparently conceding that these essential elements of the fraud that relator alleges weren't alleged in those earlier cases, Mr. Dunn and Janssen in its briefing, they're now arguing, well, these essential elements could have been inferred, but the vague and innocuous asserted disclosures, they don't provide a basis for such inferences, and in this motion, all reasonable inferences have to be drawn in favor of the non-movant, which is the relator.

11:54AM

And Mr. Dunn spent some time and he put the office-based infusion guide up on the screen, and I just want to make a couple points about that. That guide was available on Janssen's website. Relators' allegations are not based on what pamphlets Janssen made available or information it made available on its website to all doctors.

11:55AM

This is about consultative services that a team of special employees provided to select accounts and that Janssen paid outside consultants, like Xcenda, substantial fees to

provide to their best customers. And when you look at that office-based infusion guide, it specifically says that it's geared for just Remicade. It doesn't talk about all infusible products, it's really geared towards Remicade.

And also, importantly, it specifically states that the guide is for doctors who are considering opening an IOI or start infusing Remicade in their practice. What relators' allegations focus on are the free services, the IOI support, this collection of business services and support that was provided to select accounts after they had opened the IOI.

11:56AM

These IOIs were already up and running, and Janssen wanted to grow them, and, therefore, increase utilization of Remicade. So the mere references to practice management programs, business reviews, and consultants that focused on the profit opportunity from infusing Remicade, that wouldn't have put the government on notice of the elements of the fraud that the relator alleges.

Similarly, the relator's action doesn't allege the same allegations and information that Janssen has pulled together from these three earlier actions. A comparison of the asserted disclosures with the allegations in relator's complaint makes clear that the fraud that relator alleges is substantially different than the asserted disclosures, again, nearly all of which focussed on promoting the profit that could be made on Remicade, how to infuse Remicade, how to bill for

11:56AM

Remicade. Because none of the three public disclosures requirements are met, Janssen's public disclosure theory cannot trigger the public disclosure bar.

Turning, your Honor, just quickly to the original source exception, even if these information and assertions and allegations from the earlier cases were enough to trigger the public disclosure bar, Janssen's motion still fails. The relator unquestionably meets the three requirements of the original exception.

11:57AM Her knowledge is independent. We didn't hear any argument from Mr. Dunn, and you don't see it in their papers that the relator somehow just obtained her knowledge from these vague disclosures. She obtained her knowledge by providing the alleged kickbacks for 13 years. She wasn't even aware of the *Heineman* and *Greer* actions until about a year ago when Janssen disclosed them.

Janssen also doesn't dispute that the relator complied with the False Claims Act's presuit disclosure requirements. The details of her compliance with these requirements are set

11:58AM forth in the declarations submitted as Exhibit 1 to our brief.

What Janssen argues is that Ms. Long is an original source because her knowledge and information don't materially add to the asserted disclosures from the three earlier cases. Frankly, this contention is meritless, your Honor.

Under the First Circuit law, a relator's knowledge and

information materially add to publicly-disclosed allegations if it is significant or essential. That's in the *Winkelman* case, and as *Winkelman* pointed out, as the level of detail in the public disclosure increases, the universe of potentially material additions shrinks.

Here, because the asserted disclosures provide none of the essential elements and essentially no information about the fraud that relator alleges, the universe of potential material additions is really large.

11:59AM This is not a case where an opportunist relator merely adds some detail or color to a previously disclosed fraud. Here, the relator is supplying all of the essential elements, all the details, all the allegations.

Relator provides the fundamental addition of alleging that Janssen's provision of the IOI support violated the anti-kickback statute and that those violations in turn caused the recipients to cause false claims to Medicare in violation of the False Claims Act.

Your Honor closely reviewed the relator's allegations

12:00PM under the heightened standards for pleading fraud before determining that they stated a plausible fraud claim.

Respectfully, your Honor, no court would find that Janssen's hodgepodge of asserted disclosures from the earlier actions state a plausible fraud claim. As detailed in our briefing, relator provided numerous other significant and

essential additions. She adds the knowledge gained from providing the IOI support for 13 years, which has enabled her to plead the fraud with the level of particularity and support needed to move past the pleading stage and obtain the discovery needed to prove her claims.

Relator adds the specific and detailed information concerning the IOI support that constitute the illegal remuneration. These are not mere details, they're the essential allegations. Relator adds the essential information about how Janssen provided the IOI support for free. Again, this isn't a mere detail, this is an essential element of the claim.

Relator adds the essential information regarding the IOI support's value, including their substantial value beyond Remicade and SIMPONI Aria. These aren't mere details, this is a required element, as the Court held in deciding Janssen's original motion to dismiss.

Relator adds the essential information that one of Janssen's main purposes in providing the IOI support was to induce doctors to prescribe and infuse Remicade and SIMPONI Aria to Medicare beneficiaries. Again, this is an essential element, not just color.

Relator adds the information and allegations that created a plausible inference that Janssen knew that it was unlawful to provide the services to select physician practices

to induce them to prescribe and infuse Remicade and SIMPONI Aria, an essential element, not mere details.

Relator adds the essential information linking Janssen's provision of the illegal remuneration to subsequent false claims to Medicare submitted by the doctors who received the kickbacks, an essential element of a False Claims Act claim.

Those allegations don't appear in any of the earlier cases. Relator's allegations focus on the provision of the IOI support from October 2010 to the present. Like Mr. Dunn's assertions, if you read the asserted disclosures, the conduct reported in the three earlier cases all predated March 2007, and none of the information or allegation from those cases would have given any indication that Janssen's predecessor planned to continue engaging in the conduct going forward.

12:02PM

This entirely separate time period is a significant addition. The government would have no reason to believe that the conduct referenced in the earlier cases to the extent it overlapped at all with the fraud that relator has alleged would continue for another decade.

12:03PM

Relator adds the material information that is starting in July 2013. Janssen provided the IOI support to also induce providers to prescribe Remicade's successor drug, SIMPONI Aria. SIMPONI Aria had not even been approved at the time of *Heineman* and *Greer* and the *AWP* class action.

Finally, your Honor, relator has obtained substantial additional information about the alleged fraud since amending their complaint more than three years ago, and this information and evidence was only obtained because of the relator's allegations and demonstrates the materiality.

Again, relator is supplying all the essential elements that details the allegations. None of the elements of this fraud were revealed by the asserted disclosures. Because the relator's knowledge, information, allegations materially add to any prior disclosures, even if the Court were to find that the public disclosure bar was somehow triggered by the disclosure theory Janssen's fabricated, Ms. Long clearly satisfies the original source exception. In fact, if Ms. Long does not qualify as an original source, it's not clear who would meet the original source standard.

Your Honor, we respectfully request that Janssen's motion be denied.

THE COURT: Thank you. Mr. Dunn, a couple of minutes of response.

MR. DUNN: Your Honor, I know we've taken up a lot of your time already. I believe that in our papers, we've responded, you know, with citations to the relevant cases to every point Mr. Preston just made, so we will rest on our papers on that, and we believe that the key is not rhetoric but it's to look at what the cases actually say and is not

sufficient under the public disclosure bar of the original source exception.

One thing I did want to do, your Honor, it's not really a correction but it's a clarification. It's not legally relevant, but Covington has represented Janssen in this matter. It didn't represent Janssen in the prior matters that are at issue here, so I just wanted to clarify that for your Honor.

THE COURT: All right. On that point, it's clear, I don't think that's legally relevant, so, in any event. All right, thank you, all, it was really argued on both sides, and I'll take it under advisement. Thank you.

12:05PM

MR. DUNN: Thank you, your Honor.

(Whereupon, the hearing was adjourned at 12:05 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I do hereby certify that the foregoing transcript, Pages 1 through 44 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 16-12182-FDS, THE UNITED STATES OF AMERICA ex rel. JULIE LONG vs. JANSSEN BIOTECH, INC., and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

Dated June 2, 2023.

s/s Valerie A. O'Hara
_____
VALERIE A. O'HARA
OFFICIAL COURT REPORTER